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07/983,367	11/30/92	SASISEKHARAN	R MIT5981/6124

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EXAMINER	
WARE, D	
ART UNIT	PAPER NUMBER
1808	10

DATE MAILED: 03/23/94

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

a) ☒ is extended to run _____ or continues to run 3 from the date of the final rejection

b) ☒ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 03/15/94 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☒ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: Also applicants' amendment to claim 1 has been entered improperly, in that the phrase "other than hyaluronic acid" has not been properly omitted.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☐ Upon the filing an appeal, the proposed amendment ☐ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: _____

   However;

   ☐ Applicant's response has overcome the following rejection(s): _____

4. ☒ The ~~affidavit, exhibit~~ or request for reconsideration has been considered but does not overcome the rejection because of the reasons set forth in the previous Office action of 03/08/94

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER

PTOL-303 (REV. 5-89)

Claims 1-3 and 5-9 are presented for examination.

The amendment filed November 12, 1993 has been received and entered. In addition the prior art filed therewith has been received and considered as indicated on the enclosed PTO-1449. Also the cancellation of claims 4 and 10-17 is acknowledged.

Applicant's arguments filed November 12, 1993 have been fully considered but they are not deemed to be persuasive.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the reasons set forth in the previous Office action of July 6, 1993, pages 4-5.

Applicants argue that F. heparinum is readily available to the public in that accompanying documents with the amendment set forth above indicate that the organism can be obtained from American Type Culture Collection (A.T.C.C.). However, the documentation provided by applicants does not clearly indicate that the microorganism is readily available since it appears that such documentation only indicates that the microorganism is well known. Thus, this objection is maintained.

Claims 1-3 and 5-9 remain rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification, and as indicated in the Office action cited above.

Claims 1-3 and 5-9 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action of July 6, 1993, page 6.

Applicants argue that the newly amended claims should overcome this rejection. However, the newly added claim language "free of lyase activity other than heparinase II activity" and also "... other than heparinase III activity" renders the claims confusing in that it appears that applicants are claiming a purified heparinase without activity. It is suggested that applicants delete the language "other than heparinase II or III activity" since it is clear without it that the purified enzyme would be active.

Claim 6 remains vague and indefinite for the reasons cited in the previous Office action of July 6, 1993, page 6 since it remains unclear that the culture is "biologically pure". Although it is recognized that applicants have attempted to amend this claim it remains vague and indefinite without the terminology "A method for purifying heparinase I, II, and III from a biologically pure culture of Heparinum flavobacterium" and

"... in a biologically pure culture of ..." in the lysing step, respectively. In addition be sure to underline all genus and species for purposes of proper scientific nomenclature.

Furthermore applicants argue that the lysing step of claim 6 is definite since this technique is well known in the art. However, albeit the term "lysing" is well known in the art it is clear that a component is required in order to carry out the "lysing", therefore, applicants have failed to set forth clearly the procedure for lysing F. heparinum cells in that the enzyme or chemical used to carry it out is not set forth. Clearly this step is vague and indefinite without including what is used to lyse the cells since a method for purifying an enzyme is claimed herein.

Also the claim is vague and indefinite in that there appears to be no recovery step set forth for obtaining the purified product after the purification steps using cation exchange and gel permeation.

Claims 1-3 and 5-9 remain rejected under 35 U.S.C. § 103 as being unpatentable over Zimmerman et al. and Kikuchi et al. for the reasons set forth in the previous Office action of July 6, 1993, pages 8-9.

Applicants argue that there would have been no motivation to isolate new proteins from Heparinase I and that the claimed purified heparinases cannot be obvious from the cited art. However, the Zimmerman et al. reference clearly teaches that

heparinase activity is present in two proteins, one approximately 42,000-43,000 Dalton protein and one 65,000-75,000 Dalton protein (col. 2, lines 45-50). Thus, it is clear that if one of ordinary skill in the art while performing well known techniques on heparinase observed two different proteins, then the purification of heparinase I, II and III would have been an expected result of using the claimed method. The claimed method, as admitted by applicants, is clearly taught by the cited prior art. Thus, the expectation of more than one heparinase if not taught by the above cited art is at least suggested. Such suggestion in the prior art is all that is required in order to meet a case of prima facie obviousness. However, it is the opinion of the Office that the claims are clearly prima facie obvious on the basis of clear teachings represented in the cited prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Deborah K. Ware
February 23, 1994

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1808